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PATENT

Attorney Docket No.: BIO1100

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                  |  |                   |               |
|------------------|--|-------------------|---------------|
| Applicant:       | Woodbury et al.  | Art Unit:         | 1633          |
| Application No.: | 10/671,995   | Examiner          | Maria Marvich |
| Filed:           | September 26, 2003   | Confirmation No.: | 3882          |
| Title:           | RECOMBINANT FUSION PROTEINS WITH HIGH AFFINITY<br>BINDING TO GOLD AND APPLICATIONS THEREOF |                   |               |

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL SHEET**

Sir:

Transmitted herewith for the above-identified application, please find:

1. Information Disclosure Statement (2 pgs.);
2. PTO Form 1449 (4 pgs.);
3. 39 References; and
4. Return Receipt Postcard.

**CERTIFICATION UNDER 37 CFR §1.8**

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on **May 4, 2006**, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Adam Wentzel*  
Adam Wentzel

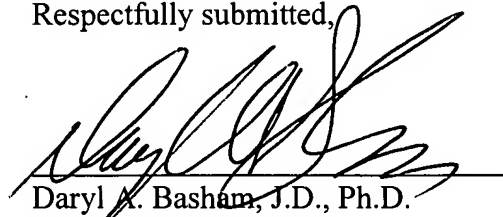
May 4, 2006

In re Application of:  
Woodbury et al.  
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No fee is deemed necessary in connection with the filing of this paper. However, if any fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of this Transmittal Sheet is enclosed.

Respectfully submitted,



Date: May 4, 2006

Daryl A. Basham, J.D., Ph.D.  
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**USPTO Customer No. 28213**



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**INFORMATION DISCLOSURE STATEMENT**

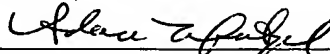
Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, the references are listed on the attached Form PTO-1449 and copies of the references are enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

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Adam Wentzel

May 4, 2006

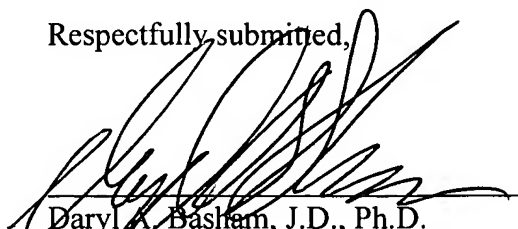
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| <b>FORM PTO-1449</b><br>U.S. Department of Commerce Patent and<br>Trademark Office | Docket No.<br>BIO1100           | Serial No.:<br>10/671,995 |
|  | Applicant(s): Woodbury et al.   |                           |
| <b>INFORMATION DISCLOSURE STATEMENT<br/>BY APPLICANT</b>                           | Filing Date: September 26, 2003 | Group Art Unit: 1633      |

### U.S. PATENT DOCUMENTS

| EXAM.<br>INITIALS |  | DOCUMENT<br>NUMBER | DATE | NAME | CLASS | SUB-<br>CLASS | FILING<br>DATE |
|-------------------|--|--------------------|------|------|-------|---------------|----------------|
|                   |  |                    |      |      |       |               |                |

### FOREIGN PATENT DOCUMENTS

| EXAM.<br>INITIALS |  | DOCUMENT<br>NUMBER | DATE | COUNTRY | CLASS | SUB-<br>CLASS | TRANSLATION<br>(YES/NO) |
|-------------------|--|--------------------|------|---------|-------|---------------|-------------------------|
|                   |  |                    |      |         |       |               |                         |

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

|  |    |   |
|--|----|---|
|  | AA | Alvarez-Icaza et al., "The Design of Enzyme Sensors Based on the Enzyme Structure" Biosensors & Bioelectronics 10:735-742, 1995   |
|  | AB | Bain et al., "Formation of Monolayer Films by the Spontaneous Assembly of Organic Thiois from Solution onto Gold" J. Am. Chem. Soc. 111:321-335, 1989   |
|  | AC | Bornstein and Balian, "Cleavage at Asn-Gly Bonds with Hydroxylamine" Methods Enzymol 47:132-145, 1977   |
|  | AD | Brown, Stanley "Metal-Recognition by Repeating Polypeptides" Nature Biotechnology 15:269-272, 1997  |
|  | AE | Chen et al., "Purification and Characterization of Recombinant Histidine-Tagged Human Platelet 12-Lipoxygenase Expressed in a Baculovirus/Insect Cell System" European Journal Biochemistry 214:845-852, 1993 |
|  | AF | Chilkoti et al., "Site-Directed Mutagenesis Studies of the High-Affinity Streptavidin-Biotin Complex: Contributions of Tryptophan Residues 79, 108, and 120" Proc. Natl. Acad. Sci. USA 92:1754- 1758, 1995   |
|  | AG | Clackson et al., "Making Antibody Fragments Using Phage Display Libraries" Nature 352:624-628, 1991   |
|  | AH | Elkind et al., "Integrated Analytical Sensors: The Use of the TISPR-1 as a Biosensor" Sensors & Actuators B54:182-190, 1999   |
|  | AI | Engel et al., "Kinetic and Structural Characterization of Adsorption-Induced Unfolding of Bovine $\alpha$ -Lactalbumin" Journal of Biological Chemistry 277/19:10922-10930, 2002                              |

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|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|  | <b>Applicant(s):</b> Woodbury et al.   |                                  |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages) |    |  |
|--|----|--|
|  | AJ | Ferapontova et. al, "Effect of Cysteine Mutations on Direct Electron Transfer of Horseradish Peroxidase on Gold" Biosensors and Bioelectronics 17:953-963, 2002  |
|  | AK | Ferapontova et. al., "Mediatorless Biosensor for H <sub>2</sub> O <sub>2</sub> Based on Recombinant Forms of Horseradish Peroxidase Directly Adsorbed on Polycrystalline Gold" Biosensors and Bioelectronics 16:147- 157, 2001 |
|  | AL | Frederick et al., "Glucose Oxidase from Aspergillus Niger" J. Biol. Chem. 265/7:3793-3802, 1990  |
|  | AM | Geoghegan, William, "Effect of Three Variables on Adsorption of Rabbit IgG to Colloidal Gold" J. Histochemistry and Cytochemistry 36/4:401-407, 1988   |
|  | AN | Grigorenko et. al., "New Approaches for Functional Expression of Recombinant Horseradish Peroxidase C in Escherichia Coli" Biocatalysis and Biotransformation 17/5:359-380, 1999   |
|  | AO | Horisberger and Clerc, "Labelling of Colloidal Gold with Protein A" Histochemistry 82:219-223, 1985  |
|  | AP | Huston et al., "Protein Engineering of Antibody Binding Sites: Recovery of Specific Activity in an Anti-Digoxin Single-Chain Fv Analogue Produced in Escherichia Coli" Proc. Natl. Acad. Sci. USA 85:5879-5883, 1988           |
|  | AQ | Jenny et al., "A Critical Review of the Methods for Cleavage of Fusion Proteins with Thrombin and Factor Xa" Protein Expr Purif. 31(1):1-11, 2003  |
|  | AR | Jonsson et al, "Real-Time Biospecific Interaction Analysis Using Surface Plasmon Resonance and a Sensor Chip Technology" BioTechniques 11:620-627, 1991  |
|  | AS | Ketema el al., "Assessment of the Performance of a Rapid, Lateral Flow Assay for the Detection of Antibodies to HIV" Journal of Acquired Immune Deficiency Syndrome 27:63-70, 2001   |
|  | AT | Kiess et al., "Glucose Oxidase from Penicillium Amagasakiense" Eur. J. Biochem. 252:90-99, 1998  |
|  | AU | Kipriyanov et al., "Single-Chain Antibody Streptavidin Fusions: Tetrameric Bifunctional scFv-Complexes with Biotin Binding Activity and Enhanced Affinity to Antigen" Hum. Antibodies Hybridomas 6(3):93-101, 1995             |
|  | AV | Ko et al., "Secretory Expression and Purification of Aspergillus Niger Glucose Oxidase in Saccharomyces Cerevisiae Mutant Deficient in PMR1 Gene" Protein Expression and Purification 25:488-493, 2002                         |

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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages) |    |   |
|--|----|---|
|  | AW | Levy et. al., "Oxidation of 4-Bromophenol by the Recombinant Fused Protein Cellulose-Binding Domain-Horseradish Peroxidase Immobilized on Cellulose" Biotechnology and Bioengineering 82:223-231, 2003                        |
|  | AX | Loertscher and Lavery, "Role of Glycosyl Phosphatidyl Inositol (GPI)-Anchored Cell Surface Proteins in T-Cell Activation" Transplant Immunology 9:93-96, 2002   |
|  | AY | Lofas and Johnsson, "Novel Hydrogel Matrix on Gold Surfaces in Surface Plasmon Resonance Sensors for Fast and Efficient Covalent Immobilization of Ligands" J. Am. Chem. Soc. Commun. 1526-1528, 1990                         |
|  | AZ | Melendez et al., "Commercial Solution for Surface Plasmon Sensing" Sensors & Actuators B35-36:212-216, 1996   |
|  | BA | Nilsson et al., "Synthetic IgG-Binding Domain Based on Staphylococcal Protein A" Protein Engineering 1/2:107-113, 1987  |
|  | BB | Park et al., "Expression of Glucose Oxidase by Using Recombinant Yeast" Journal of Biotechnology 81:35-44, 2000   |
|  | BC | Postel et al., "Structure and Denaturation of Adsorbed Lysozyme at the Air-Water Interface" Journal of Colloid and Interface Science 266/1:74-81, 2003  |
|  | BD | Ruzgas et. al., "Peroxidase-Modified Electrodes: Fundamentals and Application" Analytica Chimica Acta 330:123-138, 1996   |
|  | BE | Sano et al., "Recombinant Core Streptavidins" Journal of Biological Chemistry 270/47:28204-28209, 1995  |
|  | BF | Schlenoff et al., "Stability and Self-Exchange in Alkanethiol Monolayers" J. Am. Chem. Soc. 117:12528-12536, 1995   |
|  | BG | Scopsi et al., "Nonspecific Immunocytochemical Reactions with Certain Neurohormonal Peptides and Basic Peptide Sequences" Journal of Histochemistry and Cytochemistry 34/11:1469-1475, 1986                                   |
|  | BH | Terpe, K., "Overview of Tag Protein Fusions: From Molecular and Biochemical Fundamentals to Commercial Systems" Appl. Microbiol. Biotechnol. 60:523-533, 2003   |
|  | BI | Teske et al., "Yeast Cytochrome C Peroxidase Expression in Escherichia Coli and Rapid Isolation of Various Highly Pure Holoenzymes" Protein Expr. Purif. 19/1:139-147, 2000   |
|  | BJ | Wang et al., "Production of Active Recombinant Human Chymase from a Construct Containing the Enterokinase Cleavage Site of Trypsinogen in Place of the Native Propeptide Sequence" Biol. Chem. Hoppe-Seyler 376:681-684, 1995 |

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|--|----|---|
|  | BK | Witt et al., "Structural and Kinetic Properties of Nonglycosylated Recombinant Penicillium Amagasakiense Glucose Oxidase Expressed in Escherichia Coli" Applied and Environmental Microbiology 64:1405-1411, 1998 |
|  | BL | Woodbury et al., "Construction of Biosensors Using a Gold-Binding Polypeptide and a Miniature Integrated Surface Plasmon Resonance Sensor" Biosensors & Bioelectronics, 13:1117-1126, 1998                        |
|  | BM | Zeravik et al., "Highly Sensitive Flow-Through Amperometric Immunosensor Based on the Peroxidase Chip and Enzyme-Channeling Principle" Biosens. Bioelectron. 18:1321-1327, 2003                                   |

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